REMARKS

In the Office Action dated June 15, 2002, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121, alleging that the subject matter defined by the claims of the present invention represents the following four separate and distinct inventions:

I. Claims 1-22, drawn to a method of making insulin secreting colonies of pancreatic cells comprising bone morphogenetic protein (BMP), laminin-1 or laminin-1-containing extracellular matrix or functional derivatives, homologues, mimetics, analogues or agonists thereof in the presence or absence of antagonists of TGF-β1 or Activin A, classified in class 435, subclass 377.

II. Claims 23-25, drawn to a method of treating Type 1 diabetes or a related condition comprising transplanting insulin-secreting cells produced following *in vitro* culture in the presence of BMP, laminin-1 or laminin-1-containing extracellular matrix or functional derivatives, homologues, mimetics, analogues or agonists thereof, classified in class 424, subclass 562.

III. Claims 26 and 27, drawn to a method of treating Type 1 diabetes or a related condition comprising administering BMP or a heterodimer formed from two or more BMPs or derivatives, homologues, mimetics, analogues and/or agonists thereof, classified in class 424, subclass 426.

IV. Claims 28 and 29, drawn to a method of treatment or prophylaxis of islet/β cell hyperplasia adenoma or a related condition including pancreatic cancer comprising administering a BMP, classified in class 424, subclass 426.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect to prosecute the subject matter of Group I, claims 1-22, drawn to a method of stimulating formation of insulin secreting colonies of pancreatic cells comprising culturing pancreatic cells in the presence of bone morphogenetic protein (BMP), laminin-1 or laminin-1-containing extracellular matrix, or functional derivatives, homologues, mimetics, analogues or agonists thereof. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application.

However, pursuant to 37 C.F.R. §§ 1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized. In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement.

In the first instance, the Examiner alleges that Group I is unrelated to Groups II-IV. The Examiner admits that Groups I and II are related in that the products made by the method of Group I could be used in the method of Group II. However, the Examiner states that the methods of the two groups (Group I and Group II) per se cannot be used together. Furthermore, the insulin-secreting cells used in Group II could be obtained by means other than the method of Group I (e.g. isolation of insulin-secreting cells from pancreatic tissue). Although Groups III and IV are drawn to methods that utilize the same agonist and antagonist compounds as are used in the methods of Group I, the Examiner alleges that the mode and purpose of administration of the compounds according to Group I is distinct from that of Groups III and IV.

Furthermore, the Examiner contends that Group II is unrelated to Groups III-IV. The Examiner states that, although these groups are all drawn to methods of treating various conditions stemming from defects of insulin secreting cells, the method of Group II comprises administering insulin-secreting cells while the methods of Groups III and IV comprise administration of agonists or antagonists that affect the function of insulin secreting cells. The

Examiner contends that the methods of these groups are not disclosed as capable of use together, and are in fact mutually exclusive.

Moreover, the Examiner contends that Groups III and IV are unrelated because the methods are drawn to the use of different compounds to treat different conditions. The Examiner further states that the methods of Groups III and IV are mutually exclusive in that the compounds used are antagonistic to one another.

Applicants respectfully submit that a principal feature of the present invention resides in the recognition that certain growth factors, particularly BMP and laminin-1, play an important role in promoting differentiation of pancreatic cells. Based on this unique recognition, the present invention provides a number of methods relating to the use of these growth factors, derivatives, agonists or antagonists of these growth factors. It is respectfully submitted that the methods of Groups I-IV are all different aspects of a single invention.

The courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

The Examiner also states that the inventions have acquired a separate status in the art as evidenced by the separate classification and recognized divergent subject matter and would require independent searches. Thus, the Examiner concludes that restriction for examination purposes is proper.

Reliance on the supposed classification of the groups of claims does not establish independence and distinctness. The classification system has no statutory recognition as evidence of whether inventions are independent and distinct. The classification system is instead an aid in finding and searching for patents.

The classification system is also an unreliable basis for requiring restriction between claims to the various aspects of applicants' unitary invention, because the system exhibits considerable overlap in technical definitions. In particular, the definitions of classes and subclasses in the classification system do not prevent the Examiner from basing patentability decisions, as to claims assigned to one group, on patent references found in the classes or subclass(es) with which he associated another group of claims.

Furthermore, the classification system is a poor basis for requiring restriction between related aspects of an invention because classifications and definitions change over time. Thus, a classification that might have seemed to support restriction at a given time could change, thereby casting a shadow over the propriety of the restriction requirement later on during the term of the patents issuing from parent and divisional applications. Indeed, classifications seem largely to change in response to considerations of administrative convenience, and often in response to nothing more than growth in the number of patents in a given class or subclass. These considerations have nothing to do with whether the subject matter of patents assigned to different classifications is "independent and distinct" as those terms are used in 35 U.S.C. §121, which fact proves that basing restriction requirements on the classification system is improper.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs or to otherwise compromise the term of related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined four groups, one from the other, as presented by the Examiner.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,

Peter I. Bernstein
Registration No. 43,497

SCULLY, SCOTT, MURPHY & PRESSER
400 Garden City Plaza
Garden City, New York 11530
(516) 742-4343

PIB/XZ:dg